

PATENT
Customer No. 27874
Attorney Docket No. 29794/04001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Re Application of:

Randolph M. Howes

Application No.: 10/050,121

Filed: January 18, 2002

For: Compositions, Methods and
Apparatuses for Singlet Oxygen
Delivery

)
)
) Group Art Unit: 1616

) Examiner: Frank I. Choi

) Attorney Docket No.: 29794/04001
)
)

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

I, Randolph M. Howes, state that I am the named Applicant of the above-identified application, and am the inventor of the subject matter described and claimed therein. Prior to April 29, 1999, I have completed in this country the invention as described and claimed in the above-identified application as evidenced by the following:

1. On March 27 and 28, 1992, I attended a symposium in Photodynamic Therapy at Santa Barbara, California.
2. On the conference materials that were distributed for the conference I took notes on my ideas for methods of delivering singlet oxygen (" $^1\text{O}_2$ ") to a target site.
3. On March 29, 1992, I recorded the following notes:

"RMH

3/29/92

– one could also use $^1\text{O}_2^*$ in an irrigating system for wound cavities such as emphyemas or peritonitis or a wound surface – this would have both bacteriocidal & tumoricidal activity" (Exhibit 1.)

"– an added advantage of injectable $^1\text{O}_2^*$ is that there is literally no limit to depth of treatment such as seen with PDT in which the light can penetrate only to 5 mm or where diffusion techniques have to be employed" (Exhibit 2.)

"– one could use endoscopes to place the treating $^1\text{O}_2^*$ virtually anywhere in the body utilizing the injection technique" (Exhibit 2.)

4. In September 1993, I tested the inventive concept on myself.

5. On September 14, 1993, I recorded the following notes as I tested the invention on myself:

"9/14/93 10PM RMH – lesion 0.5 cm dia

– will inj. keratosis on right shoulder with H_2O_2 & NaOCl – 0.1 cc each with 25 gauge needle & 1 cc tuberculin syringe

– will use 1% xylocaine with 1:100,000 epi

10:15 PM – inj. with xylocaine

10:25 PM – inj. with NaOCl – painful

" " H_2O_2 – turned white

11:30 – still painful but turning black

12:00 MN – looks like early scab" (Exhibit 3.)

6. On September 15, 1993, I recorded the following notes based on observations of the September 14, 1993-injection site:

- "9/15/03¹ – injected lesion now black with eschar
- looks like it killed it
- will try again
- will wait longer for local anesth." (Exhibit 3.)

7. On September 21, 1993, I recorded the following notes based on observations of the September 14, 1993-injection site:

- "9/21/02² – still not sloughed off but lesion is definitely dead" (Exhibit 3.)

8. On March 15, 1996, I repeated the test of the invention on myself, this time reversing the order of the reactant injections.

9. On March 15, 1996, I recorded the following notes as I repeated the invention on myself:

- "RMH – 3/15/96 will repeat injection but will use dermal nevus or keratosis.
- 1% xylocaine 1:100,000 epi
- nevus on Left forearm <0.3 cm dia
- inj. 0.1 cc H₂O₂ first then NaOCl
- can't inj. both together – needles too awkward
- seemed to work better with NaOCl first, then follow with H₂O₂" (Exhibit 4.)

10. On March 16, 1996, I recorded the following notes relating to the injection site:

¹ Note that I incorrectly recorded the date as "9/15/03". In fact, I recorded the notes on September 15, 1993.

² Note that I incorrectly recorded the date as "9/21/02". In fact, I recorded the notes on September 21, 1993.

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"3/16/96 11AM – did do as well as with H₂O₂ first but did turn black, like with
PDT" (Exhibit 4.)

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

Date: _____

Dr. Randolph M. Howes

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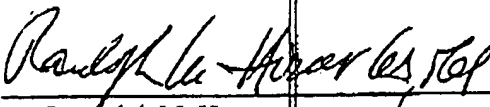
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Date: 11/21/04


Dr. Randolph M. Howes